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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/582,328	07/19/2000	WOLF-GEORG FORSSMANN	P65678US0	4260

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JACOBSON HOLMAN PLLC
400 SEVENTH STREET N.W.
SUITE 600
WASHINGTON, DC 20004

EXAMINER	
MAYER, SUZANNE MARIE	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 10/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/582,328	FORSSMANN ET AL.	
	Examiner	Art Unit	
	Suzanne M. Mayer, Ph.D.	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 July 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *41-48 and 50-52* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *41-47 and 50-52* is/are rejected.

7)☒ Claim(s) *48* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 June 2000* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *8-09-2000*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I, claims 41-48 and 50-52, in the reply filed on July 30, 2004 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Priority

2. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

3. The information disclosure statement (IDS) submitted on August 9, 2000 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner. Please see the attached PTOL-1449.

Oath/Declaration

4. The Oath/Declaration is objected to because it does not identify the mailing address of each inventor. A mailing address is an address at which an inventor customarily receives his or her mail and may be either a home or business address. The mailing address should include the ZIP Code designation. The mailing address

may be provided in an application data sheet or a supplemental oath or declaration.

See 37 CFR 1.63(c) and 37 CFR 1.76.

Claim Rejections - 35 USC § 101

5. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 41-48 and 50-52 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The serine protease inhibitors, as recited in the claims, all exist in their natural form found in nature or are found in the cellular precursor thereof and possess the biological and functional properties of the naturally occurring polypeptides and therefore does not constitute patentable subject matter absent recitation of "isolated and purified" in the preamble.
See *American Wood v. Fiber Disintegrating Co.*, 90 U. S. 566 (1974); *American Fruit Growers v. Brogdex Co.*, 283 U. S. 1 (1931); *Funk Brothers Seed Co. v. Kalo Inoculant*, 33 U. S. 127 (1948); and *Diamond v. Chakrabarty*, 206 USPQ 193 (1980).

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 51 recites the limitation "0.01 to 1000 mg per kg of body weight.....". There is insufficient antecedent basis for this limitation in the claim. The specification of

the instant application specifically defines that medicaments are preferably administered in amounts of from 1 to 100 mg/kg of the patient's body weight. There is no mention of less than 1 or greater than 100 mg/kg in the specification.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 41-47, 50 and 52 rejected under 35 U.S.C. 102(e) as being anticipated by Moore et al. Moore et al. teach an amino acid sequence (SEQ ID No: 149) which is a protein that has a domain with four cysteines, and a sequence of 13 amino acids between the first and second cysteine, a sequence of 18 amino acids between the second and third cysteines, and a sequence of two amino acids between the third and fourth cysteines. Furthermore, this sequence possesses 100% identity to SEQ ID No: 7 of the instant application and claim and can be located between the first and second cysteines. The Moore et al. sequence (SEQ ID No: 149) also has 100% sequence identity to SEQ ID Nos: 19 and 21 of the instant application and claim 43, in where these sequences can be located between the second and third cysteines of the motif described in claim 41. The Moore et al. sequence also possesses a sequence that is 100% identical to that recited in claim 44 where AT and AM can be found between the

third and fourth cysteines according to the motif defined in claim 41. The Moore et al. sequence is also 100% identical to the limitations set forth in claim 45 because it is 100% identical to SEQ ID No: 30 (amino acids 23-77 of the Moore et al. sequence) of this claim because R_1 is 22 amino acids and R_2 is 477 amino acids.

Claims 41-44 are further rejected over Moore et al., because on p. 37 of the specification several more sequences are taught which meet the limitations of the instant claims. Specifically, SEQ ID Nos: 357-362 meet the limitations of claim 41. Claim 42 is rejected because SEQ ID No: 362 according to Moore et al. has a sequence which meets the limitations set forth in the instant claim when SEQ ID No: 10 is chosen; also SEQ ID No: 15 of the instant claim is 100% identical to SEQ ID No: 359 according to Moore et al. Claim 43 is rejected because SEQ ID No: 25 of the instant claim is anticipated by SEQ ID No: 359 according to Moore et al. and SEQ ID No: 22 is anticipated by SEQ ID No: 362 according to Moore et al. Claim 44 is further rejected because the limitations that a serine protease inhibitor according to claim 41 where the sequence between the third and fourth cysteines are chosen from AL, SM and AM are disclosed in SEQ ID Nos: 357-359 according to Moore et al. Claim 47 is rejected because SEQ ID No: 359 from Moore et al. is a fragment of VATKI-2 (SEQ ID No: 2) and corresponds to amino acids 297-333.

Claims 50 and 52 are rejected because Moore et al. teach that the polypeptide of SEQ ID No: 149 and the DNA encoding it can be used in pharmaceutical compositions for administration to patients (see p. 257, lines 12-20). The gene that codes SEQ ID No: 149 is expressed primarily in the heart, tonsils, Hodgkin's lymphoma,

neuroblastoma, leukocytes and lungs (see p. 39, lines, 23-24). Therefore, the polynucleotides and polypeptides are useful as to diagnosis and treatment of various conditions related to diseases occurring in the tissue where it is specifically expressed.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claim 51 is rejected under 35 U.S.C. 103(a) as being unpatentable over Moore et al. in further view of common and standard techniques used by pharmacologist, nurses and doctors.

Moore et al. teach that SEQ ID No: 149 and the DNA encoding it can be used in pharmaceutical compositions for administration to patients (see p. 257, lines 12-20) to treat various diseases. Moore et al. does not, however, teach a dosage range which is useful for administration to a patient.

However, the determination of an effective dosage amount would be obvious to one of ordinary skill in the art because this is a crucial and vital part of medical school/training for all skilled artisans. Claim 52 is included in this rejection because one skilled in the art, such as a medical doctor, would be able to empirically determine the effective dose of a serine protease inhibitor to treat a disease such as chronic inflammatory processes especially given the broad range recited in claim 51 as 0.01-

1000 mg/kg as a basis to work from. Finally, a reasonable expectation of success would be anticipated to determine an effective dose in the range of 0.01-1000 mg/kg of body weight of the patient because they do not hand out medical, nursing or pharmacology licenses unless competently qualified individuals pass the rigorous requirements to obtain these licenses.

Conclusion

11. Claims 41-47 and 50-52 are rejected. Claim 48 is objected to because it is dependent from a rejected base claim but would be allowed if rewritten in independent form. Furthermore, this claim would be allowable because the term 'being' of the instant claim is determined to be closed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suzanne M. Mayer, Ph.D. whose telephone number is 571-272-2924. The examiner can normally be reached Monday to Friday from 8.30am to 5.00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SMM
22 Septempber, 2004

ROBERT A. WAX
PRIMARY EXAMINER